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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,553	03/29/2004	Yehia A. Massoud	309,426	8288
38137 7590 02/02/2009 ABELMAN, FRAYNE & SCHWAB 666 THIRD AVENUE, 10TH FLOOR NEW YORK, NY 10017				
EXAMINER				
MAL HAO'D				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/810,553

Applicant(s)

MASSOUD, YEHAIA A.

Examiner

HAO D. MAI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2008.
2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8, 9, 12-19 and 23-34 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 8-9, 12-19, 23-34 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SI-08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claim 14 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

- Claim 14 is a dependent claim but there is no indication which claim it is dependent on.
- Claims 29 and 16 recites limitations to a treatment plan, which is a subcombination usable with the subcombination of the surgical guide. However, Applicant has failed to recite a combination (e.g. system, assembly, etc.) in order to combine the two subcombinations of the surgical guide and the treatment plant.
- Claims 30 and 17-19 recites limitation to a cutting device, which is a subcombination usable with the subcombination of the surgical guide. However, Applicant has failed to recite a combination (e.g. system, assembly, etc.) in order to combine the two subcombinations of the surgical guide and the cutting device.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 112, first paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 8-9, 12-19, and 23-28, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

- Independent claim 8 recites the window's ledge having "a first thickness and at least a second thickness differing from the first thickness to correspond to thickness variations of a bony wall lateral to said maxillary sinus... ", which does not have support from the original disclosure and therefore is considered to be new matter.

Claim Rejections - 35 USC § 112, second paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 13-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 13 recites the limitation "said inferior...ledge portion", which lacks antecedent basis.
- Claims 14-15 each recites the limitation "said peripheral edges" (plural), which lack antecedent basis. Only a singular peripheral edge is defined in claim 8.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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11. Claims 23-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Pompa (5,320,529).

Pompa discloses a method comprising the steps of: providing a treatment plan including three dimensional images which characterizes the maxillary sinus and maxillary bone structures of the patient (column 2 lines 60-63; column 4 lines 41-43; column 6 lines 19-43; column 7 lines 13-19); providing a surgical guide 16 having a window 38 that is shaped and dimensioned to correspond with the patient's maxillary sinus and maxillary bone structures (Fig. 5). Pompa further discloses placing the surgical guide over a portion of an alveolar ridge 20 and adjacent teeth (Fig. 5); cutting a portion of the maxillary bone 14 using a bur 17 traversing along a ledge forming window 38; and providing bone graft to the maxillary bone and sinus (Fig. 5). Pompa also disclose the step of providing computerized tomography of the maxillary bone and sinus and the associate wall shapes, dimensions, etc. (column 7 lines 13-19). The bur 17 is shown to have a depth guide 17 set at a predetermined distance from the distal end of the cutting blade (Fig. 5). The surgical guide 16 is disclosed to be made from acrylic (column 4 lines 66-67).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 8-9, 12-15, and 31-34, are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenberg (5,558,622).

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Regarding claim 8, Greenberg discloses a surgical guide 54 comprising: a curvilinear-shaped structure 56 having a three-dimensional window 60 (Fig. 4). The window 60 is formed by a peripheral edge that defines a ledge.

The claim language "for performing sinus elevation and penetrating a lateral wall of a maxillary sinus of a patient", "for placement adjacent said wall of the maxillary sinus", and "for placement over a portion of said wall of the maxillary sinus to define a surgical field to perform the sinus elevation", are functional language reciting intended uses. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The surgical guide 54 as disclosed by Greenberg is capable of being used for performing sinus elevation and penetrating a lateral wall of a maxillary sinus of a patient; the curvilinear-shaped structure 56 is capable of being placed adjacent the lateral wall of the maxillary sinus; and the window 60 is capable of being placed over a portion of said wall of the maxillary sinus to define a surgical field to perform the sinus elevation.

Greenberg discloses the invention substantially as claimed except for the ledge having first and second thicknesses differing from each other to correspond to thickness variation of a bony wall lateral to said maxillary sinus and the window's peripheral edge including differing surface contours that correspond to and align with uniquely shaped contours formed along surface portions of the wall defining the maxillary sinus and maxillary bone of the patient. Nonetheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Greenberg by making the window's peripheral edge and ledge having thicknesses and/or contours suitable for the procedure, i.e. thicknesses and/or contours that match with the anatomy where the procedure is being performed. Such modifications are

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a change(s) in shape, configuration, and/or dimension, which is a design choice well within the skill of the artisan obtainable via routine experimentation in order to achieve optimum results.

As to claim 9, the curvilinear-shaped structure 56 is shown to include a lower portion having a surface 59 (Fig. 4) capable of being positioned over an alveolar ridge of the maxillary bone and/or adjacent teeth of said patient; and an upper portion (best pointed at by reference number 56 is shown in Fig. 4) extending upward from the lower portion surface capable of being positioned adjacent to the lateral wall of the maxillary sinus in proximity to said surgical field.

As to claim 12, Greenberg fails to disclose the curvilinear-shaped structure being made from an acrylic material. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the structure from an acrylic material since it is a suitable well known material that can be used to manufacture such structure.

As to claims 13-15 and 31-34, the window 60 is shown to have a lower, mesial, posterior, and superior ledge portions capable of corresponding in shape to an inferior, mesial, posterior, and superior portions of the sinus; the window is capable of providing an outline of a coronal, anterior, posterior, and apical aspect along an X-Y plane of the lateral wall of the maxillary sinus, or an outline along a Z-Y plane and Z-X plane of the patient for penetrating the lateral wall of the maxillary sinus.

8. Claims 16 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenberg in view of Pompa (5,320,529).

Greenberg discloses a surgical guide substantially as claimed. However, Greenberg fails to disclose the surgical guide further comprise a treatment plan including CT-scan and three-dimensional images characterizing the various areas of the patient's sinus and bone structures. It is well known in the medical field to utilize CT-scan and three-dimensional images of the sites where the surgical procedure is going to be performed. For example, Pompa

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discloses providing a treatment plan including a CT scan and 3D-imaging of maxillary sinus and maxillary bone structures of the patient (column 2 lines 60-63; column 4 lines 41-43; column 6 lines 19-43; column 7 lines 13-19). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate such treatment plan which includes CT-scan and 3-D images of the maxillary sinus and the maxillary bone structures of the patient in order to aid the surgeon(s) in having an accurate and precise understanding in what needs to be done during the procedure. Such CT-scan and 3-D images also aid in producing a before-and-after comparisons for the treatment.

9. Claims 17-19 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenberg in view of Boukhris (6,235,035).

Greenberg discloses the invention substantially as claimed except for the cutting device as claimed in claims 30 and 17-19. Boukhris discloses a drill/bur (Fig. 1) capable of tracing along the ledge of the window of Greenberg's device. The bur comprises: an elongated shaft (E) having opposing first and second ends, said first end is capable of being inserted into a rotary device; a cutting blade (A) coupled to the second end of the shaft (E); and a depth guide (B) extending transversely from the shaft and spaced a predetermined distance (d) from the distal end of the cutting blade. The disclosed bur's depth guide (B) is capable of interfacing and traversing along Greenberg's window ledge. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the usage of Boukris' bur as needed for bone recovering procedures while using Greenberg's device.

As to claim 18, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Greenberg/Boukhris by making the depth guide traverse the shaft a distance in a range of approximately 5-10 mm from the outer edge of the cutting

edge since it has been held that (1) discovering an optimum or workable ranges, and/or (2) changing a component's size, involves only routine skill in the art. See *MPEP* §§ 2144.05.

Response to Arguments

12. Applicant's arguments have been considered but are not persuasive and/or moot in view of the new ground(s).

Applicant argued Pompa disclosing a conventional circular bore, not a window that is sized larger than the cutting edge of the bur according to the applicant's invention. However, note that such feature is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding the newly introduced limitation "varying thickness", such limitation lacks support from the originally filed disclosure and is considered to be new matter. Applicant is required to show support from such limitation from the original disclosure in order to overcome the rejection.

Regarding the claims rejections under Greenberg, applicant argued that Greenberg teaches away or defeats the purpose of the present invention. Note that Applicant is structurally claiming an apparatus, and as such only positively claimed structural limitations carry patentable weight. If the prior art satisfy the claimed structural limitation and is reasonably capable of performing the claimed functions, then it meets the claim.

Applicant is generally trying to define the structures of the invented device by claiming it to be corresponding to the uniquely shape of the wall(s) of the maxillary sinus and maxillary bone of a particular patient. This approach of defining the invention is very broad because it gives an indefinite limitation to the claimed structures since every patient's bone is essentially

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different to another. And this is when considering only humans, not other living species having maxillary sinus and bone, as the claimed patient. The Applicant argued that the present invention is to be customized to the patient instead of being a standard as disclosed by Greenberg. Note that such customization is not recited in the claims.

Conclusions

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAO D. MAI whose telephone number is (571)270-3002. The examiner can normally be reached on Monday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached on (571) 272-4964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hao D Mai/
Examiner, Art Unit 3732

/Cris L. Rodriguez/
Supervisory Patent Examiner, Art Unit 3732